Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

Report Date:04/29/2009

## **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011406 059601906 059601706 059601506	09/04/02 10/10/01 02/23/00 08/22/01	729 729 729 729	50 (1) 50 (1) 49 (1) 50 (1)	33(700) 38(696) 31(685) 40(697)	55.6 54.1 52.5 54.0	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
				Fen	nale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011406 059601906 059601706 059601506	09/04/02 10/10/01 02/23/00 08/22/01	735 734 734 731	50 (5) 50 (5) 50 (5) 50 (5)	35(701) 36(693) 38(708) 35(705)	64.3 63.0 64.3 60.9	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 257
Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
All Organs: Benign Tumors								
<b>g</b>		42/50 (84%) 32/50 (64%)	41/50 (82%)	25/49 (51%)		27/50 (54%) 29/50 (58%)	32/50 (64%)	29/50 (58%)
verall Incidence	Total	140/199 (70.35%)	Mean 70.26%	SD 15.66%	Total	117/200 (58.5%)	Mean 58.5%	SD 4.12%
All Organs: Malignant Tumors					•••••		•••••	
		31/50 (62%) 29/50 (58%)	36/50 (72%)	23/49 (47%)		22/50 (44%) 31/50 (62%)	38/50 (76%)	36/50 (72%)
verall Incidence	Total	119/199 (59.8%)	Mean 59.73%	SD 10.37%	Total	127/200 (63.5%)	Mean 63.5%	SD 14.27%
All Organs:  Malignant and Benign To	umors						•••••	
		49/50 (98%) 41/50 (82%)	47/50 (94%)	37/49 (76%)		36/50 (72%) 44/50 (88%)	43/50 (86%)	42/50 (84%)
verall Incidence	Total	174/199 (87.44%)	Mean 87.38%	SD 10.43%	Total	165/200 (82.5%)	Mean 82.5%	SD 7.19%
All Organs: Hemangioma					•••••		•••••	
_		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	3/50 (6%)
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	6/200 (3%)	Mean 3%	SD 2.58%
All Organs: Hemangiosarcoma								
		4/50 (8%) 1/50 (2%)	3/50 (6%)	4/49 (8%)		2/50 (4%) 3/50 (6%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.04%	SD 2.87%	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male		Female	
#All Organs: Hemangiosarcoma or He	emangioma					
nomangiosarooma or no	omangioma -	4/50 (8%) 2/50 (4%)	4/50 (8%) 4/49	(8%)	3/50 (6%) 3/50 (6%) 4/50 3/50 (6%)	) (8%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04% SD	2.03% Total	13/200 (6.5%) Mean 6.5% S	D 1%
#All Organs: Histiocytic Sarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	2/50 (4%) 1/50 (2%) 0/50 4/50 (8%)	0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD	0% Total	7/200 (3.5%) Mean 3.5% S	D 3.42%
#All Organs: Malignant Lymphoma: H or Undifferentiated Cell <sup>*</sup>						
		2/50 (4%) 0/50 (0%)	2/50 (4%) 0/49	(0%)	7/50 (14%) 18/50 (36%) 27/5 9/50 (18%)	50 (54%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2% SD	2.31% Total	61/200 (30.5%) Mean 30.5% S	D 18.36%
#All Organs: Mesothelioma: Benign, I						
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1% SD	2% Total	` ,	D 0%
All Organs: Mesothelioma: Malignan	ıt					
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1% SD	2% Total	0/200 (0%) Mean 0% S	D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Osteosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteo	ma				•••••			
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Adrenal Cortex: Adenoma								
		7/49 (14%) 6/50 (12%)	9/50 (18%)	3/49 (6%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	25/198 (12.63%)	Mean 12.6%	SD 4.98%	Total	0/199 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Mali	gnant							
	_	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Adrenal Cortex:								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Be							•••••	
		0/49 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Co	mplex							
•	•	0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Ma	alignant							
•	J	0/49 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma: Be								
	. J, 22p.o.	0/49 (0%) 1/49 (2%)	0/50 (0%)	1/49 (2%)		0/49 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	2/197 (1.02%)	Mean 1.02%	SD 1.18%	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
*Bone Marrow: Hemangioma								
· ·		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma	•••••							
		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/196 (1.02%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Malig	ınant							
<u> </u>	•	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone:								
Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 262 Report Date: 04/29/2009

**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: WATER

			Male				Female	
Bone: Osteosarcoma								
00.000		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma or Osteoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Sarcoma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 263

			Male			Female	
*Brain: Meningioma: Benign, Mal	lignant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD	0% Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	Mean 0% SD	,	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
*Clitoral/Preputial Gland: Adenoma		0/50 (0%) 1/49 (2%)	0/48 (0%) 0/49	(0%)	0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51% SD	1.02% Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/48 (0%) 0/49	(0%)	0/50 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/196 (0%)	Mean 0% SD	0% Total	0/47 (0%) 0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma							
Overall Incidence	Total	0/50 (0%) 1/49 (2%) 1/196 (0.51%)	0/48 (0%) 0/49  Mean 0.51% SD	(0%) 1.02% Total	0/50 (0%) 0/47 (0%) 0/190 (0%)	0/43 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ontrol Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Hemangioma								
-		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
#Esophagus: Squamous Cell Carcinoma	• • • • • • • • • • • • • • • • • • • •							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Harderian Gland: Adenoma 6/50 (12%)(10%)(6%)4/50 (8%)(2%)(18%)5/50 (10%)6/50 (12%)**Overall Incidence** Total 19/199 (9.55%) Mean 9.53% SD 2.46% Total 20/200 (10%) Mean 10% SD 6.73% #Harderian Gland: Carcinoma 0/50 (0%)1/50 (2%)(2%)0/50 (0%)2/50 (4%)**Overall Incidence** Total Mean 0% SD 0% Total 6/200 (3%) Mean 3% SD 1.15% 0/199 (0%) #Harderian Gland: Carcinoma or Adenoma 6/50 (12%)(10%)(6%)(10%)3/50 (6%)(20%)5/50 (10%)8/50 (16%) **Overall Incidence** SD 6.22% Total 19/199 (9.55%)Mean 9.53% SD 2.46% Total 26/200 (13%)Mean 13% #Harderian Gland: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/199 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% \*Heart: Hemangioma (0%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 266

			Male				Female	
Heart: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Sarcoma					•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Carcinoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma							•••••	
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Leiomyoma						•••••		
<b>,</b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male			Female	
#Intestine Large: Colon/Rect Leiomyosarcoma	um:						
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (	(0%) Mean 0%	SD 0%
Intestine Small: Duodenum: Adenoma							
		1/50 (2%) 1/50 (2%)	3/50 (6%)	0/49 (0%)	0/50 0/50	(0%) 1/50 (2%) (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 2.52%	Total 1/200 (	(0.5%) Mean 0.5%	SD 1%
Intestine Small: Duodenum: Carcinoma							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total 0/200 (	,	SD 0%
Intestine Small: Duodenum: Leiomyosarcoma		•••••					
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (	(0%) Mean 0%	SD 0%
Intestine Small: Duodenum: Polyp Adenomatous							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (	,	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Carcinoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Jejunum: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 Mean 0% 0/200 (0%) **Overall Incidence** Total 0/199 (0%) SD 0% Total Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) #Intestine Small: Jejunum: Polyp Adenomatous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1.02% SD 0% Total 1/199 (0.5%) Mean 0.51% Total 0/200 (0%) Mean 0% #Intestine Small: Site Unspecified: Adenoma 1/50 (2%)(0%)0/50 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** 5/199 (2.51%) Mean 2.5% SD 2.52% 1/200 (0.5%) SD 1% Total Total Mean 0.5% #Intestine Small: Site Unspecified: Carcinoma (0%)0/50 2/50 (0%)1/50 (2%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/199 (1.51%)Mean 1.5% SD 1.91% Total 2/200 (1%) Mean 1% SD 1.15% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Site Unspecified: Carcinoma or Adenoma 1/50 (2%)(10%)(0%)1/50 (2%)(4%)(0%)(2%)(0%)1/50 0/50 3/200 (1.5%) Overall Incidence Total 7/199 (3.52%) Mean 3.5% SD 4.43% Total Mean 1.5% SD 1.91% #Intestine Small: Site Unspecified: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) ..... #Intestine Small: Site Unspecified: Leiomvosarcoma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/199 (0%) Mean 0% Total 0/200 (0%) Mean 0% #Intestine Small: Site Unspecified: Polyp Adenomatous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/199 (0.5%) Mean 0.51% SD 1.02% SD 0% Total Total 0/200 (0%) Mean 0% \*Islets, Pancreatic:

SD 2.57%

1/49

1/49

4/196 (2.04%)

Total

(2%)

Total

3/49

1/50

5/195

(6%)

(2%)

Mean 2.53%

(2.56%)

Adenoma

**Overall Incidence** 

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Report Date: 04/29/2009

1/49

SD 0%

Mean 2.04%

(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Control Animal Groups Report Date:04/29/2009
RAL

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			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma or Adenoma								
		3/49 (6%) 1/50 (2%)	1/50 (2%)	0/46 (0%)		1/49 (2%) 1/49 (2%)	1/49 (2%)	1/49 (2%)
Overall Incidence	Total	5/195 (2.56%)	Mean 2.53%	SD 2.57%	Total	4/196 (2.04%)	Mean 2.04%	SD 0%
Kidney: Renal Tubule: Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 3.78%	Total	0/199 (0%)	Mean 0%	SD 0%
(idney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 3.78%	Total	0/199 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor

act/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 272

			Male				Female	
Kidney: Renal Tubule: Hemangioma								
ū		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Malign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma				•••••			•••••	•••••
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Liver: Fibrous Histiocytoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Liver: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/198 (1.01%)	Mean 1.02%	SD 1.18%
Liver: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	2/50 (4%)	1/49 (2%)		1/49 (2%) 2/50 (4%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	4/198 (2.02%)	Mean 2.02%	SD 1.63%
Liver: Hepatoblastoma								
•		17/50 (34%) 1/50 (2%)	4/50 (8%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
overall Incidence	Total	22/199 (11.06%)	Mean 11%	SD 15.71%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Liver: Hepatocellular Adenoma								
		36/50 (72%) 29/50 (58%)	27/50 (54%)	18/49 (37%)		14/49 (29%) 19/50 (38%)	27/50 (54%)	19/49 (39%)
overall Incidence	Total	110/199 (55.28%)	Mean 55.18%	SD 14.52%	Total	79/198 (39.9%)	Mean 39.84%	SD 10.52%
_iver: Hepatocellular Carcinoma			•••••					
		14/50 (28%) 24/50 (48%)	19/50 (38%)	14/49 (29%)		8/49 (16%) 10/50 (20%)	14/50 (28%)	3/49 (6%)
Overall Incidence	Total	71/199 (35.68%)	Mean 35.64%	SD 9.43%	Total	35/198 (17.68%)	Mean 17.61%	SD 9.08%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Liver:	Hawatahi							
Hepatocellular Carcinor	та от нератові	25/50 (50%) 24/50 (48%)	21/50 (42%)	14/49 (29%)		8/49 (16%) 10/50 (20%)	14/50 (28%)	4/49 (8%)
verall Incidence	Total	84/199 (42.21%)	Mean 42.14%	SD 9.67%	Total	36/198 (18.18%)	Mean 18.12%	SD 8.24%
_iver:					•••••			
Hepatocellular Carcinor	ma or Hepatoce	ellular Adenoma 42/50 (84%) 37/50 (74%)	34/50 (68%)	28/49 (57%)		17/49 (35%) 27/50 (54%)	31/50 (62%)	22/49 (45%)
verall Incidence	Total	141/199 (70.85%)	Mean 70.79%	SD 11.24%	Total	97/198 (48.99%)	Mean 48.9%	SD 11.77%
Hepatocellular Carcinor Hepatoblastoma Overall Incidence	Total	46/50 (92%) 37/50 (74%) 146/199 (73.37%)	35/50 (70%) Mean 73.29%	28/49 (57%) SD 14.4%	Total	17/49 (35%) 27/50 (54%) 97/198 (48.99%)	31/50 (62%) Mean 48.9%	22/49 (45%) SD 11.77%
iver: Hepatocholangiocarcin	oma	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/198 (0%)	Mean 0%	SD 0%
iver: Hepatocholangioma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/40 /00/	0/50 /00/)	0/40 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER

Animal Groups Report Date:04/29/2009

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
*Liver: Ito Cell Tumor Benign		0/50 (00/)	0/50 /00/)	0/40 (00/)		0/40 (00/)	0/50 (00/)	0/40 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/198 (0%)	Mean 0%	SD 0%
*Liver: Plasma Cell Tumor Maligna	ant				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma				•••••		•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
*Lung: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Lung: Alveolar/Bronchiolar Adenoma 15/50 (30%)(14%)1/50 (2%)(4%)1/50 (2%)6/50 (12%)3/50 (6%)7/200 (3.5%) SD 1.91% **Overall Incidence** Total 32/199 (16.08%) Mean 16.07% SD 9.64% Total Mean 3.5% \*Lung: Alveolar/Bronchiolar Carcinoma (6%) 3/50 (24%)(10%)2/50 (4%)(12%)(2%)4/50 (8%)6/50 (12%) **Overall Incidence** Total Mean 12.05% SD 8.15% Total 15/200 (7.5%) Mean 7.5% SD 5.26% 24/199 (12.06%) \*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 16/50 (32%)15/50 (30%)12/49 (24%)2/50 (4%)8/50 (16%)(4%)(20%)(18%) 10/50 9/50 **Overall Incidence** Total 53/199 (26.63%) SD 5.44% 21/200 (10.5%) SD 7.55% Mean 26.62% Total Mean 10.5% \*Lung: Fibrosarcoma 1/50 (2%)0/50 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/199 (0.5%) 0/200 (0%) SD 0% **Overall Incidence** Total Mean 0.5% SD 1% Total Mean 0% \*Lung: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
ung: Hemangiosarcoma								
riemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ung: Plasma Cell Tumor Mali						•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ung: Sarcoma				•••••		•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Lymph Node: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
-ymph Node: Plasma Cell Tumor Malignant				•••••	•••••			•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node: Sarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node, Bronchial: Hemangiosarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node, Mandibular: Fibrous Histiocytoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Inc

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (09/)	0/50 (09/)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
-ymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt							
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node, Mesenteric: Fibrous Histiocytoma				•••••		•••••		
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ute: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: WATER

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maliç			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ntrol Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Mammary Gland: Carcinoma or Adenoma	<u> </u>							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Mammary Gland: Fibroadenoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom	a or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom			•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		3/50 (6%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 282

			Male				Female	
#Mesentery: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Nose: Mast Cell Tumor Malign								
maer con ramer mang.		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary							
. apinoma oquamous o	аршоша	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(2%)(0%)0/50 (0%)0/50 1/200 (0.5%) **Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total Mean 0.5% SD 1% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)(0%) 0/50 **Overall Incidence** 0/199 (0%) SD 0% SD 2% Total Mean 0% Total 2/200 (1%) Mean 1% Choriocarcinoma 0/50 (0%)0/47 (0%)0/49 (0%)(2%) 1/50 **Overall Incidence** Total 1/196 (0.51%) Mean 0.5% SD 1% \*Ovary: Cystadenoma 1/50 (2%)(4%)0/49(0%)1/50 (2%)**Overall Incidence** 4/196 (2.04%) Total Mean 2.06% SD 1.74% \*Ovary: **Fibrous Histiocytoma** 0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Vehicle: WATER

Page: 284 Report Date: 04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

	Male		Female	
*Ovary: Granulosa Cell Tumor Benign				
Granulosa Celi i umor benign		0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	1/50 (2%) 1/196 (0.51%)	Mean 0.5%	SD 1%
Overall incluence		, ,		
*Ovary:				
Granulosa Cell Tumor Malignant		0/50 (0%)	0/47 (0%)	0/49 (0%)
		0/50 (0%)	0/47 (070)	,
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%) 1/50 (2%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.5%	SD 1%
*Ovary:		•••••	• • • • • • • • • • • • • • • • • • • •	•••••
Hemangioma		0.770		2/12 (22/)
		0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma				
•		0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups Page: 285

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** \*Ovary: Leiomyosarcoma (0%)(0%)(0%)(0%) 0/50 **Overall Incidence** Total 0/196 (0%) Mean 0% SD 0% \*Ovary: Luteoma 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/196 (0%) Mean 0% SD 0% \*Ovary: **Plasma Cell Tumor Malignant** 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/196 (0%) Mean 0% \*Ovary: Teratoma Benign 0/50 (0%) (0%)0/50 (0%)**Overall Incidence** 0/196 (0%) Mean 0% SD 0% Total **Teratoma Malignant** (0%)(0%) 0/47 0/49 0/50 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: WATER

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 286

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Ovary: Tubulostromal Adenoma						0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence					Total	1/50 (2%) 1/196 (0.51%)	Mean 0.5%	SD 1%
*Pancreas: Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								•••••
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
*Pancreas: Carcinoma or Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
*Pituitary Gland: Pars Distalis o Adenoma								
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		3/48 (6%) 2/48 (4%)	4/48 (8%)	2/47 (4%)
Overall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	11/191 (5.76%)	Mean 5.75%	SD 1.97%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Vehicle: WATER

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Animal Groups Report Date:04/29/2009

Page: 287

Species: MICE Strain: B6C3F1

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma											
		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	0/47 (0%)			
verall Incidence	Total	0/193 (0%)	Mean 0%	SD 0%	Total	0/191 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Dist Carcinoma or Adenom					•••••						
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		3/48 (6%) 2/48 (4%)	4/48 (8%)	2/47 (4%)			
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	11/191 (5.76%)	Mean 5.75%	SD 1.97%			
Pituitary Gland: Pars Inte Adenoma	rmedia:										
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	1/47 (2%)			
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	1/191 (0.52%)	Mean 0.53%	SD 1.06%			
Pituitary Gland: Pars Inte Carcinoma or Adenom	rmedia:				•••••						
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	1/47 (2%)			
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	1/191 (0.52%)	Mean 0.53%	SD 1.06%			
Prostate: Adenoma	•••••										
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)							
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%							

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

Page: 288

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male			Female	
*Prostate: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/48 (0%)			
		0/50 (0%)	0/00 (0/0)	0/40 (070)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%			
*Prostate: Hemangioma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Carcinoma			•••••				
		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total 0/200 (0%)	Mean 0% SD 0%	
*Salivary Glands:			•••••				
Carcinoma or Adenoma		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total 0/200 (0%)	Mean 0% SD 0%	
*Salivary Glands:			•••••				
Mast Cell Tumor Malignan	t	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/198 (0%)	Mean 0%	SD 0%	0/50 (0%) Total 0/200 (0%)	Mean 0% SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

1. Way2000

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 289

			Male				Female	
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrosarcoma				•••••		•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Myxosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/199 (0%) 0/200 (0%) **Overall Incidence** Total Mean 0% SD 0% Total Mean 0% SD 0% **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/199 (0%) #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/199 (0%) Mean 0% Total 0/200 (0%) Mean 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/199 (0%) SD 0% **Overall Incidence** Total Mean 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 1/50 (2%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Vehicle: WATER

			Male				Female	
#Skin: Basal Cell Carcinoma ( NOS)	or Basosquamo	us Tumor (malignant or						
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, Tumor (benign, malign	Basal Cell Ader		0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	thoma, Trichoep Total	pithelioma 1/50 (2%) 0/50 (0%) 2/199 (1.01%)	1/50 (2%) Mean 1%	0/49 (0%) SD 1.15%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basosquamous Tumor		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#Skin: Fibroma		0/50 (004)						
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 292

Report Date:04/29/2009

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	, Sarcoma, Myx	koma, Myxosarcoma, o	r					
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		2/50 (4%) 4/50 (8%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	12/200 (6%)	Mean 6%	SD 2.31%
#Skin: Fibrosarcoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 4/50 (8%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	6/200 (3%)	Mean 3%	SD 3.46%
#Skin: Fibrosarcoma, Sarcoma Histiocytoma	ı, Myxosarcom	a, or Fibrous						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%) 4/50 (8%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	12/200 (6%)	Mean 6%	SD 2.31%
Skin: Fibrous Histiocytoma		0/50 (00/)		0/40 /00/		0/50 (00/)	4/50 (001)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 2.83%
Skin: Granular Cell Tumor Be	nign							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0 /8)				0/30 (0/6)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 293

Report Date:04/29/2009

			Male				Female	
#Skin: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Myxosarcoma								
myxoodi ooma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:			•••••			•••••		
Neurofibrosarcoma or Se	chwannoma (ı	malignant or NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Neurofibrosarcoma, Neurofi malignant or NOS)	broma, or	Schwannoma (benign,						
manghant of 1100)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma			•••••			•••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Skin: Schwannoma Malignant			•••••			•••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosguamous Tumor (malignant or NOS), or Carcinoma 1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/199 (0.5%) SD 1% SD 0% Overall Incidence Total Mean 0.5% Total 0/200 (0%) Mean 0% **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)SD 1% SD 0% **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% Total 0/200 (0%) Mean 0% #Skin: Squamous Cell Papilloma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (0%)(0%) 0/50 0/50 **Overall Incidence** 1/199 (0.5%) SD 1% Total 0/200 (0%) SD 0% Total Mean 0.5% Mean 0% Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (0%) (0%) 0/50 (0%)(2%)0/50 (0%)(0%)1/50 0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% Squamous Cell Papilloma, Papilloma, or Keratoacanthoma (0%)(0%)(0%)(0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0.5% SD 1% SD 0% Total 1/199 (0.5%) Total 0/200 (0%) Mean 0%

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Report Date: 04/29/2009

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

ntrol Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Trichoepithelioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Sebaceous Gland: Carcinoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Spinal Cord: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ORAL

Report Date: 04/29/2009

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Species: MICE Strain: B6C3F1

Vehicle: WATER Length of Study: CHRONIC

Male Female \*Spleen: **Fibrous Histiocytoma** 0/49 (0%)(0%)(0%)0/48 (0%)(0%)(0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0% Total 0/195 (0%) Mean 0% SD 0% \*Spleen: Hemangioma 0/49 (0%)0/48 (0%)(0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total Mean 0.5% SD 1% Total 0/195 (0%) Mean 0% SD 0% 1/196 (0.51%) \*Spleen: Hemangiosarcoma (2%) 2/49 (4%)1/50 1/48 (2%)(2%)(0%)1/50 (2%)0/48 (0%)**Overall Incidence** 2/195 (1.03%) SD 1.19% Total 6/196 (3.06%) Mean 3.08% SD 1.25% Total Mean 1.03% \*Spleen: Mast Cell Tumor Malignant 0/49 (0%)0/48(0%)(0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** 0/196 (0%) SD 0% SD 0% Total Mean 0% Total 0/195 (0%) Mean 0% \*Spleen: Plasma Cell Tumor Malignant (0%)0/49 0/50 (0%)0/47 0/48 0/49 (0%)0/50 (0%)(0%)0/50 0/48 (0%)**Overall Incidence** Total 0/196 (0%)Mean 0% SD 0% Total 0/195 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 298

Report Date:04/29/2009

			Male				Female	
Stomach, Forestomach: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma c Overall Incidence	r <b>Papillon</b> Total	na Squamous 0/50 (0%) 0/50 (0%) 3/199 (1.51%)	2/50 (4%) Mean 1.51%	1/49 (2%) SD 1.92%	Total	1/50 (2%) 1/50 (2%) 3/200 (1.5%)	0/50 (0%) Mean 1.5%	1/50 (2%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (00()	2/50 (40/)	0/40 (00/)		4/50 (20/)	0/50 (0%)	1/50 (20/)
		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/49 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 299

Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Stomach, Glandular: Carcinoma 0/50 (0%)(0%)(0%)0/50 (0%)(0%)(2%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Stomach, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% 0/199 (0%) \*Testes: Adenoma 0/50 (0%)1/50 (2%)(0%)1/50 (2%)**Overall Incidence** Total 2/199 (1.01%) Mean 1% SD 1.15% \*Testes: Hemangiosarcoma 0/50 (0%)(2%)0/50 (0%)**Overall Incidence** 1/199 (0.5%) Mean 0.51% SD 1.02% Total \*Thymus: Thymoma Benign 0/49 (0%)(0%) 0/46 0/46 0/49 (0%)0/44 (0%)0/46 (0%)**Overall Incidence** Total 0/181 (0%) Mean 0% SD 0% Total 0/185 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
Thymus: Thymoma Malignant								
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
verall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Γhymus: Thymoma: Benign, Malign				•••••				
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
verall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma								
		1/50 (2%) 3/50 (6%)	3/50 (6%)	0/48 (0%)		1/50 (2%) 1/49 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.5%	SD 3%	Total	8/199 (4.02%)	Mean 4.01%	SD 2.3%
*Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma			•••••	•••••				
		1/50 (2%) 3/50 (6%)	3/50 (6%)	0/48 (0%)		1/50 (2%) 1/49 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.5%	SD 3%	Total	8/199 (4.02%)	Mean 4.01%	SD 2.3%
#Tissue NOS: Carcinoma			•••••	•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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Report Date:04/29/2009

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 302 Report Date:04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
#Tissue NOS: Plasma Cell Tumor Malignar	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tongue: Squamous Cell Carcinoma o								
•	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 303 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
#Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tooth: Odontoma				•••••	•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
· ·		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Hemangiosarcoma				•••••				
•		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Maligna							•••••	
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
Urinary Bladder: Sarcoma		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Uterus: Adenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Jterus: Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
terus:			•••••			•••••		
Hemangioma					Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
·····						, ,		
Jterus: Hemangiosarcoma						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Verall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

	Male			Female	
tUterus:					
Leiomyoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)		
verall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Uterus:				•••••	
Leiomyosarcoma					
-			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
veran mondence			` ,		
Uterus:					
Polyp Stromal					
			1/50 (2%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence		Total	5/200 (2.5%)	Mean 2.5%	SD 1%
Uterus:					
Sarcoma Stromal			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%) 0/50 (0%)	0/30 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal					
Carcoma Stromar or 1 oryp Stromar			1/50 (2%)	2/50 (4%)	1/50 (2%)
			1/50 (2%)	. ,	, ,
Overall Incidence		Total	5/200 (2.5%)	Mean 2.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
Uterus: Schwannoma Malignant								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
				•••••				
Vagina: Squamous Cell Carcinor	na							
•						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
······································					••••			
Squamous Cell Papillom	а					1/50 (2%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0,00 (0,0)	0/00 (0/0)
verall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Zymbal's Gland:								
Carcinoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	,	,		0/50 (0%)	,	,
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Carcinoma or Adenoma		•••••						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied